K011057

JUN - 6 2001

PREMARKET NOTIFICATION
510(k) SUMMARY
(As Required By 21 CFR 807.92)

807.92 (a):

1. *Submitter's Name:* OraSure Technologies, Inc.
   Address: 150 Webster St., Bethlehem, PA 18015
   Telephone Number: (610) 882-1820
   Contact Person: R. Sam Niedbala, Ph.D., BCFE
   Date Prepared: March 30, 2001

2. *Device Name:*
   Proprietary Name: Intercept™ Oral Fluid Drug Test Oral Specimen Collection Device
   Usual Name: Intercept™ Oral Specimen Collection Device
   Classification Name: Blood Specimen Collection Device

3. *Device to Which Substantial Equivalence Is Claimed:*
   OraSure® Oral Specimen Collection Device; K970357

4. *Description of Device:*
   The Intercept™ Oral Fluid Drug Test Oral Specimen Collection Device consists of a treated absorbent cotton fiber pad affixed to a nylon stick (Collection Pad) and a preservative solution in a plastic container (Specimen Vial). The Collection Pad is impregnated with a mixture of common salts and gelatin, creating a hypertonic environment which produces an osmotic gradient across the buccal and gingival mucosae. The Pad is placed in contact with the gingival mucosa (between the lower cheek and gum) which enhances the flow of mucosal transudate onto the absorptive cotton fibers of the Pad. Following the collection period, the Collection Pad is removed from the mouth and placed into a Specimen Vial. The vial contains a preservative solution which serves to inhibit the growth of oral microorganisms recovered on the Collection Pad. The vial is sealed with a plastic cap and transported to a laboratory for processing and testing.

5. *Intended Use Statement:*
   The Intercept™ Oral Fluid Drug Test Oral Specimen Collection Device is intended for use in the collection, preservation, and transport of oral specimens. Oral specimens collected with the Intercept™ Oral Specimen Collection Device can be used to detect cocaine and cocaine metabolites, cannabinoids, phencyclidine, amphetamine, methamphetamine, opiates, barbiturates and methadone with the OraSure Technologies Intercept™ MICRO-PLATE EIAs.

6. *Comparison of Technological Characteristics:*
   The Intercept™ Oral Fluid Drug Test Oral Specimen Collection Device is substantially equivalent to the OraSure® Oral Specimen Collection Device, K970357. Both devices share the same major components (collection apparatus and transport container containing a preservative solution) and are intended for collecting an oral fluid specimen, and for containing and transporting that specimen. The oral specimens collected with the Intercept™ device, however, can be used to detect cocaine and cocaine metabolites, cannabinoids, phencyclidine, amphetamine, methamphetamine, opiates, barbiturates and methadone with the OraSure Technologies Intercept™ MICRO-PLATE EIAs as demonstrated in the premarket notifications for the assays (K001197, K000399, K992918, K002375, K993208, K981341, K001976, K002010). OraSure Technologies considers this device to be substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

OraSure Technologies, Inc.
R. Sam Niedbala, Ph.D., BCFE
Chief Science Office
150 WEBSTER ST.
BETHELEHEM, PA 18015-1389

FEB 06 2015

Re: K011057
Trade/Device Name: Intercept Oral Fluid Drug Test Oral Specimen Collection Device
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood specimen collection device
Regulatory Class: II
Product Code: PJD
Dated: March 30, 2001
Received: April 6, 2001

Dear Dr. Niedbala:

This letter corrects our previous Substantially Equivalent (SE) letter of June 6, 2001.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K011057

Device Name: Intercept™ Oral Fluid Drug Test Oral Specimen Collection Device

Indications For Use:

The Intercept™ Oral Fluid Drug Test Oral Specimen Collection Device is intended for use in the collection, preservation, and transport of oral specimens. Oral specimens collected with the Intercept™ Oral Specimen Collection Device can be used to detect cocaine and cocaine metabolites, cannabinoids, phencyclidine, amphetamine, methamphetamine, opiates, barbiturates and methadone with the OraSure Technologies Intercept™ MICRO-PLATE EIAs.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Fred Lacy

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K011057

Prescription Use ✓ **OR** **Over-The-Counter Use** _____
(Per 21 CFR 801.109)

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